IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS AG, NOVARTIS PHARMACEUTICALS CORPORATION, MITSUBISHI TANABE PHARMA CORPORATION, and MITSUI SUGAR CO., LTD.,	)	
Plaintiffs,	)	C.A. No. 15-0150-LPS
v.	)	
EZRA VENTURES, LLC,	)	
Defendants.	)	

DEFENDANT EZRA VENTURES, LLC'S BRIEF IN SUPPORT OF ITS MOTION FOR JUDGMENT ON THE PLEADINGS UNDER FRCP 12(c)

Dated: January 25, 2016

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I. STATEMENT OF THE NATURE AND STAGE OF PROCEEDINGS

Plaintiffs assert patent infringement under the Hatch-Waxman Act in response to Defendants' filing of their respective ANDAs. The parties currently are engaged in fact discovery with a *Markman* hearing scheduled for June 16, 2016.

II. SUMMARY OF ARGUMENT

1. Defendant Ezra Ventures, LLC ("Ezra")[1] respectfully moves for judgment on the pleadings under Fed. R. Civ. P. 12(c) with respect to the validity of the Patent Term Extension ("PTE") of United States Patent No. 5,604,229 ("the '229 patent") past the expiration date of United States Patent No. 6,004,565 ("the '565 patent").

2. As outlined in Ezra's counterclaims, the extension of the '229 patent should be ruled invalid or required to be disclaimed for the time past the expiration date of the '565 patent for three independent reasons, each of which are independent grounds for this motion.

3. First, the extension violates 35 U.S.C. § 156 because it effectively extends the life of more than one patent for the same FDA regulatory period.

4. Second, the extension violates well established Supreme Court precedent that the subject matter of an expired patent is dedicated to the public, free for anyone to use.

5. Third, the extension renders the '229 patent invalid for double patenting.

6. Termination of the improper PTE will revert the at-issue '229 patent back to its February 2014 natural expiration date and thus will effectively moot this ANDA case against

[1] Ezra has conferred with other Defendants Actavis and HEC per the Scheduling Order, who do not join the motion at this time.

Ezra and prevent any claim construction hearing on June 6, 2016 thereby conserving resources of all parties and this Court.[2]

III. STATEMENT OF FACTS

Two patents are relevant to the instant motion. The '565 patent, which is not asserted in this case[3], claims a method of administering fingolimod itself in an effective amount in order to manipulate lymphocyte activity. (Ex. A, '565 patent) It expires first on September 23, 2017. Plaintiffs listed this patent in the Orange Book for their fingolimod product Gilenya®, and by doing so assert that it claims fingolimod in at least one patent claim. (Ex. B, Orange Book listing for Gilenya®)

The '229 compound patent, which is asserted against Ezra in this action, includes claims 9 and 10 (among others) that claim the fingolimod molecule. (Ex. C, '229 patent) This patent discloses that these compounds, including fingolimod, are useful as immunosuppressants. The application that led to the '229 patent was filed on June 17, 1994 and issued on February 18, 1997, and was originally scheduled to expire on February 18, 2014. However, right before the '229 patent expired, Plaintiffs obtained a patent term extension under 35 U.S.C § 156 for an extension of five years (the maximum available under the statute). Thus the '229 patent presently expires on February 18, 2019, approximately a year and a half after the '565 method patent. (Ex. B) Notably, the '229 patent and the '565 patent are not related through any common patent application.

[2] Although this Court "generally" disfavors dispositive motions, this motion on legal issues should be considered as it will undeniably conserve the resources of the parties and the Court without needing to resolve disputed material questions of fact. This motion is also not entirely "case dispositive" because, *inter alia*, the counterclaim of coordinated Defendants, HEC Pharm Co., Ltd., HEC Pharm Group and HEC Pharm USA Inc., on U.S. Patent No. 8,324,283 would continue. Ezra has not counterclaimed on the '283 patent. *See*, Scheduling Order, ¶ 20.

[3] Ezra has filed a Paragraph III certification with respect to this patent.

Each ground for this motion presents a purely legal issue: can a broader compound patent be extended past the expiration of a later-issued patent claiming the method of using a compound claimed in the broader compound patent, thereby *de facto* extending the second method patent, without violating 35 U.S.C. § 156; can the compound patent be extended past the earlier-expiring method patent that uses the compound without violating the bedrock principle that the public may practice an expired patent; and, can the compound patent be extended beyond the expiration of the later-issued method patent without violating the jurisprudence on double patenting? Thus, this is a case where judgment on the pleadings is entirely appropriate.[4]

IV. ARGUMENT

"Judgment on the pleadings should only be granted if it is clearly established that no material issue of fact remains to be resolved and that the movant is entitled to judgment as a matter of law." *Rodriguez v. Stevenson*, 243 F. Supp. 2d 58, 62 (D. Del. 2002). A Rule 12(c) motion is especially useful where, as here, "only questions of law remain to be decided by the district court." 5C Charles A. Wright & Arthur R. Miller, *Federal Practice & Procedure*(s) 1367 (2004) (citing cases.)

In evaluating a motion for judgment on the pleadings, a court may consider the pleadings, exhibits attached to the pleadings, matters of public record, and any documents "integral to or explicitly relied upon" in the pleadings. *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997); *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993). Where the factual allegations in a complaint contradict a document attached to the pleadings, however, the document controls. *See ALA, Inc. v. CCAIR, Inc.*, 29 F.3d

[4] *See e.g., Genzyme Corp. v. Anchen Pharmaceuticals, Inc.*, Case No. 10-cv-00512-GMS (D. Del. October 31, 2011) (granting motion for judgment because the sole remaining issue before the Court was a question of law.); *BuySAFE, Inc. v. Google Inc*., 964 F. Supp. 2d 331 (D. Del. 2013) (Stark, J.)(granting motion for judgment on the pleadings of invalidity under § 101).

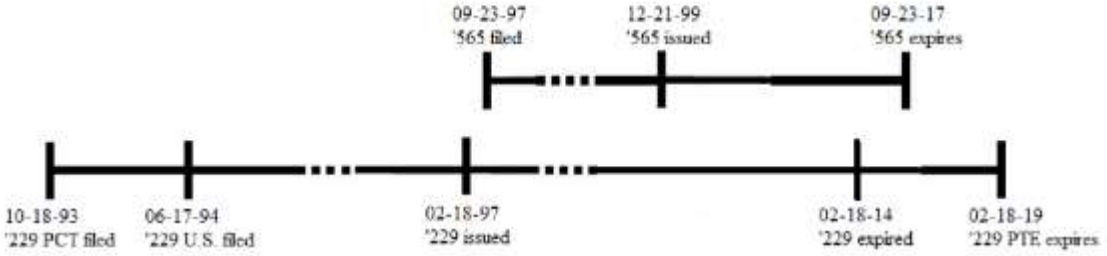
855, 859 n.8 (3d Cir. 1994); *Sisk v. Sussex Cnty.*, Civ. No. 11-121-RGA, 2012 WL 1970879 (D. Del. June 1, 2012).

A. The Patent Term Extension of the '229 Patent Violates 35 U.S.C. § 156

The right to a patent term extension (PTE) based upon FDA regulatory review is codified at 35 U.S.C. § 156. Under this section, the term of a patent may be extended for a period of time, but in no event shall more than one patent be extended for the same regulatory review period. 35 U.S.C. § 156(c)(4) (2012); see also 37 C.F.R. 1.785, MPEP 2751. This is known as the "one patent per period rule."

The patent term extension granted for the '229 compound patent effectively violates § 156(c)(4)'s limitation on extending only one patent for each regulatory review period. The '229 patent claims fingolimod (the active ingredient of the branded product Gilenya®). *See, e.g.* claim nos. 9 and 10. The '565 method patent claims a method of using fingolimod affecting the manipulation of lymphocytes. *See, e.g.*, claim nos. 1-3. One cannot practice the method claimed in the '565 patent without making and using fingolimod, thereby infringing the compound claims of the '229 compound patent.

As diagrammed below, the application for the '565 patent was filed after the '229 patent was filed and issued, but will expire before the '229 patent's full term plus extension expires. Plaintiffs applied for and received patent term extension based on claims 1-3, 7-10, 35-36, 39-40, 42, 48 and 52 of the '229 patent. (Ex. D, Application for PTE, and Ex. E., PTE Certificate).



By applying for and obtaining the PTE on the ’229 patent, the inventors effectively acquired a PTE for both the ’229 and ’565 patents. The public cannot practice the inventions under either patent until the PTE expires on the ’229 patent. The statute and regulations issued specifically prohibit acquiring an extension on more than one patent for any one regulatory review period. 35 U.S.C. § 156(c)(4) (2012); see also 37 C.F.R. 1.785, MPEP 2751.

Furthermore, Plaintiffs could have avoided this situation. In applying for and obtaining the PTE, Plaintiffs had the option to pick amongst their various Orange Book listed patents to extend the term. See 37 C.F.R. 1.785, MPEP 2761 (“When plural patents are found to be eligible for patent term extension based on the same regulatory review of a product, the final determination under 37 CFR 1.750 will provide a period of time (usually one month) for the patent owner to elect the patent for which extension is desired.”). They could have chosen to extend the ’565 patent, with the public free to make the compounds of the ’229 patent, including fingolimod, at expiration in 2014 and only foreclosed from the specific use of the fingolimod

compound claimed by the '565 patent.[5] This would not have extended protection on more than one patent.

This does not present a situation similar to that of *Merck & Co., Inc. v. Hi-Tech Pharmacal Co., Inc.*, 482 F.3d 1317 (Fed. Cir. 2007). In that case, the patents were related and a terminal disclaimer on the later patent was required in order for that later patent to issue. Thereafter, Merck attached the PTE to the patent with a terminal disclaimer. The Federal Circuit noted that the legislative history of § 156 indicated that Congress was aware of concerns regarding extending related patents, and furthermore noted that "Congress chose not to limit the availability of a patent term extension to a specific parent or continuation patent but instead chose a flexible approach which gave the patentee the choice." *Merck*, 482 F.3d at 1323. Indeed, if a patentee had several related patents covering its product (a common occurrence) an inability to extend one past the other commonly-expiring related patents could result in none of the patents being eligible for PTE, an obviously wrong conclusion based on the intent of the statute. Hence, the Federal Circuit ruled that the previously terminally disclaimed patent at issue was eligible for a later PTE. *Merck*, 482 F.3d at 1324.

Here, however, Plaintiffs have two unrelated patents with no such terminal disclaimer, a different situation than in *Merck.* Furthermore, Plaintiffs here had a choice that would have avoided the situation of obtaining an effective extension on the two unrelated patents, options that were not available to the patentee in *Merck.* The policy reasons and statutory intent underlying *Merck* do not apply here; rather, the statute is clear that only one patent can be extended per regulatory period.

[5] This could have protected the Plaintiffs' brand product Gilenya® because the only FDA-approved indication for fingolimod appears to be within the claims of the '565 patent.

Because Plaintiffs' patent term extension extends the term of more than one patent, the extension is improper under 35 U.S.C. § 156 and should either be invalidated entirely or invalidated to the extent that it goes beyond the expiration of the '565 patent. 35 U.S.C. § 282(c) ("Invalidity of the extension of a patent term or any portion thereof under section 154(b) or 156…")

B. The Patent Term Extension of the '229 Compound Patent Beyond the Expiration of the '565 Method Patent Violates the Fundamental Principle That Expired Patents Are Dedicated To the Public

A fundamental rubric of patent law is that the subject matter of an expired patent is dedicated to the public, free for anyone to make, use or sell. *Singer Mfg. Co. v. June Mfg. Co.*, 163 U.S. 169, 185 (1896) ("It is self evident that on the expiration of a patent the monopoly created by it ceases to exist, and the right to make the thing formerly covered by the patent becomes public property. It is upon this condition that the patent is granted."); *Kellogg Co. v. Nat'l Biscuit Co.*, 305 U.S. 111, 120 (1938); *Scott Paper Co. v. Marcalus Mfg. Co.*, 326 U.S. 249 (1945); *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 230 (1964) ("Finally, and especially relevant here, when the patent expires the monopoly created by it expires, too, and the right to make the article—including the right to make it in precisely the shape it carried when patented—passes to the public."); *Kimble v. Marvel Entm't, LLC*, 135 S. Ct. 2401, 2407 (2015) ("And when the patent expires, the patentee's prerogatives expire too, and the right to make or use the article, free from all restriction, passes to the public.").

The '565 patent, which claims the use of the fingolimod compound for the treatment of MS, expires in September 2017. But the public is not free to use that invention thereafter because the '229 compound patent has been extended, and the '229 patent protects the compound fingolimod (as well as innumerable other compounds). As such, one cannot practice the use of

fingolimod upon patent expiry because the fingolimod molecule itself cannot even be made (much less used) because of the illegitimate PTE. An expired patent will be unavailable for use by the public.

In applying for and obtaining the PTE, Plaintiffs had the option to pick amongst their various patents to extend the term. They could have chosen to extend the '565 method patent, with the public free to make the compounds of the '229 compound patent after expiration in 2014 and only foreclosed from a specific use of fingolimod. The public policy of expired patents being available for practice by all would not have been violated. However, with the '229 compound patent extended, there is no way to practice the '565 method patent upon its expiry because one is not permitted make the fingolimod molecule in the first place.

Thus, the extension granted to the '229 compound patent should be invalidated, or at minimum adjusted. 35 U.S.C. § 282(c). One alternative remedy would be that the public has an implied license to practice the '229 patent to the extent the public can practice the expired subject matter of the '565 patent, with the extension remaining in effect for other potential uses of fingolimod. Such a remedy avoids removing the extension entirely, while still allowing the public to practice the expired subject matter of the '565 method patent.

C. The Patent Term Extension of the '229 Patent Is Invalid For Double Patenting

1. The Patent Term Extension is Invalid as § 101 Double Patenting

The doctrine of double patenting seeks to prevent the unjustified extension of patent exclusivity beyond the term of a patent. Double patenting is "statutory" when it violates 35 U.S.C. § 101, which states that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain ***a patent*** therefor . . ." 35 U.S.C. § 101 (emphasis added). The statute permits "a

patent," singular. A double patenting rejection thus precludes a person from obtaining more than one valid patent for the "same invention." *In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985). "The ban on double patenting ensures that the public gets the benefit of the invention after the original period of monopoly expires." *Abbvie Inc. v. Mathilda and Terence Kennedy Inst. Of Rheumatology Trust*, 764 F.3d 1366, 1373 (Fed. Cir. 2014).

The '565 patent, which claims the precise use of fingolimod for the treatment of a disease, expires in September 2017. However, the public does not get the benefit of that invention thereafter because the '229 patent has been extended beyond September 2017 and the '229 patent protects the fingolimod compound. The patent term extension of the '229 patent should be invalidated for statutory double patenting because the claims to methods of using fingolimod in the '565 patent and the '229 patent claims to the fingolimod compound cover the same invention.

According to the MPEP, Section 806.05, "Where two or more related inventions are claimed, the principal question to be determined in connection with . . . a rejection on the ground of double patenting is whether or not the inventions as claimed are distinct. . . . If nondistinct inventions are claimed in separate applications or patents, double patenting must be held. . . ." To invalidate the '229 patent term extension based on double patenting, the '565 patent's claimed method of using fingolimod must be nondistinct from the '229 patent claims to the fingolimod compound itself.

Claim 1 of the '565 patent reads as follows:

> 1. A method for accelerating the lymphocyte homing activity of the immune system of a mammal, while simultaneously maintaining the IL-2 mRNA expressing ability of T cells in the mammal, ***comprising*** introducing an effective amount of an accelerated lymphocyte homing composition ***comprising*** 2-

> amino-2[2-(4-octylphenyl)ethyl]propane-1,3-diol hydrochloride to the mammal.

'565 patent, col. 24, l. 60-67 (emphasis added). This claim includes the word "comprising" twice, and thus the subject matter is essentially a method for accelerating lymphocyte homing activity of the immune system including introducing an accelerated lymphocyte homing composition. The accelerated lymphocyte composition itself includes 2-amino-2[2-(4-octylphenyl)ethyl]propane-1,3-diol hydrochloride, which is the chemical name of fingolimod hydrochloride. Fingolimod *hydrochloride* is claimed in each of the '229 patent compound claims claiming fingolimod because each of the '229 patent compound claims end with "or a pharmaceutically acceptable salt thereof." (Complaint D.I. 1, ¶¶ 21-25)(See also '565 patent, col. 4, ln. 41-55)(confirming that compounds, including fingolimod, used in the method of the '565 are found in the '229 patent)

a. Fingolimod Hydrochloride Is Not Distinct From the '565 Patent Claims to Compositions Comprising Fingolimod Hydrochloride

The inventions of (1) a composition *comprising* fingolimod hydrochloride as claimed in the '565 patent and (2) fingolimod hydrochloride as claimed in the '229 patent respectively constitute a combination and a subcombination. According to MPEP § 806.05(c), "inventions are distinct if it can be shown that a combination as claimed: (A) does not require the particulars of the subcombination as claimed for patentability (to show novelty and nonobviousness), and (B) the subcombination can be shown to have utility either by itself or in another materially different combination." This rule is conjunctive, and thus both (A) and (B) must be shown for the combination and subcombination to be distinct. The combination (composition comprising fingolimod hydrochloride) does not work without the subcombination (fingolimod

hydrochloride), meaning (A) is not shown. Thus, the inventions of (1) a composition comprising fingolimod hydrochloride and (2) fingolimod hydrochloride are not distinct.

b. An Accelerated Lymphocyte Homing Composition Is Not Distinct From A Method For Accelerating Lymphocyte Homing Activity Comprising Introducing Said Composition

The inventions of (1) an accelerated lymphocyte homing composition as claimed in the ’229 patent and (2) a method for accelerating lymphocyte homing activity comprising introducing such a composition as claimed in the ’565 patent respectively constitute a product and process of using the product. According to MPEP § 806.05(h), “A product and a process of using the product can be shown to be distinct inventions if either or both of the following can be shown: (A) the process of using as claimed can be practiced with another materially different product; or (B) the product as claimed can be used in a materially different process.” This rule is disjunctive, so neither (A) nor (B) must be true for a product and a process of using the product to be indistinct inventions. As claimed, a method for accelerating lymphocyte homing activity comprising introducing an effective amount of an accelerated lymphocyte homing composition as claimed in the ’565 patent cannot be practiced with a product that is materially different from an accelerated lymphocyte homing composition as claimed in the ’229 patent. As claimed, whether an accelerated lymphocyte homing composition can be used in a materially different process than a method for accelerating lymphocyte homing activity depends on the effect of the method and the mode of action of the composition.

According to the ’565 patent specification,

> The instant invention involves compositions and methods that suppress the immune response in mammals in a novel way. This immunosuppression results from accelerating lymphocyte homing.

'565 patent, col. 2, l. 36-39. Thus, the compositions and methods specifically suppress the immune system, and the immunosuppression is an effect of the accelerating lymphocyte homing of the method and the composition as claimed in claim 1. Further, the specification states:

> In one embodiment, the invention provides a method of suppressing the immune response by accelerating lymphocyte homing . . . . This embodiment can be used to suppress the immune response in a mammal and comprises administering an ALH-immunosuppressive compound. The ALH-immunosuppressive compounds of this invention functionally act by directing lymphocytes to specific locations or lymphoid tissues.

Id. col. 2, l. 59-67.

> In other embodiments, the invention provides a method of accelerating lymphocyte homing in a mammal, where a ALH-immunosuppressive composition is used. . . . In another embodiment, the invention provides a method for reversibly reducing the number of circulating immune cells in a mammal. These embodiments comprise introducing an ALH-immunosuppressive composition . . . .

Id. col. 5, l. 8-20. According to the '565 patent, the method of claim 1 directed to accelerating lymphocyte homing, as claimed, and the accelerated lymphocyte homing composition itself, as claimed, both act to affect immunosuppression upon a mammal.

As claimed, an accelerated lymphocyte homing composition cannot be used in a materially different process. In columns 6-8, the '565 patent lists the various conditions and diseases for which the compositions are useful. In numerous of these conditions, scientific literature references explicitly indicate pathology involving the immune system. Therefore, the '565 patent compositions are all useful for conditions and/or diseases specifically involving problems of the immune system and cannot be used in materially different processes than affecting the immune system. As such, an accelerated lymphocyte homing composition and a process for accelerating lymphocyte homing activity of the immune system are not distinct,

claim 1 of the ’565 patent is not a distinct invention from the compound fingolimod hydrochloride, and the ’229 patent term extension should be invalidated based on statutory double patenting.

2. The Patent Term Extension Is Invalid For Obviousness-Type Double-Patenting

Obviousness-type or nonstatutory double patenting arises when the claimed subject matter in an application is obvious over a commonly-owned patent such that the issuance of a second patent would provide an unjustified extension of the term of the right to exclude granted by a patent. The two patents in question must have at least one common inventor, common applicant, and/or be either commonly owned/assigned. MPEP 804. Both patents at issue here have common inventors Kunitomo Adachi and Kenji Chiba, making obviousness-type double patenting a consideration. Likewise, the safe harbor provision under 35 U.S.C. § 121 is irrelevant as the applications are not related.

The Federal Circuit’s *Gilead Sciences, Inc. v. Natco Pharma Limited* decision provides a further basis why the extension period of the ’229 compound patent extending beyond the ’565 method patent is improper. *Gilead* addresses the specific question of whether a patent that issues after, but expires before, another patent may otherwise qualify as a double patenting reference for the earlier-issued but later-expiring patent. *Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1211-12 (Fed. Cir. 2014).[6] The Federal Circuit expanded the double patenting doctrine and held that a patent that issues after, but expires before, another patent may qualify as a double patenting reference for that other patent. *Id.* In doing so, the court determined that the patent expiration date, and not the patent issue date, should determine whether a claim qualifies as a

[6] The Federal Circuit confirmed that double patenting continues to apply where the same invention is claimed in two patents or a later-expiring patent would be obvious in light of the earlier in *Abbvie Inc.* 764 F.3d 1366.

double patenting reference.[7] The patentee may then be required to file a terminal disclaimer limiting the term of the later-expiring patent to the term of the earlier-expiring patent, even though that patent issued first. *Id.*

Though the *Gilead* decision does not specifically address the rule's application to patents extended by PTE, it is undoubtedly applicable to the '229 and '565 patents. As discussed above, the '229 patent was filed and issued first, but does not expire until after the '565 patent due to the grant of the patent term extension. The patents do not claim priority to a common application. The dates reflect a similar situation as in the *Gilead* case, with the prior-expiring patent having issued after the later-expiring patent.

The second inquiry is whether the later expiring '229 compound patent would have been obvious in light of the method of using fingolimod claimed in the '565 patent. A method of using a compound claim will either anticipate or otherwise make obvious claims directed to the compound itself. Thus, had the '565 patent been filed first, it would have anticipated or made obvious the compound claims in the '229 patent.

Consequently, applying the Federal Circuit's holding evaluating the patents' expiration dates rather than issuance dates, the '565 patent serves as an obviousness-type double patenting reference to the now later-expiring '229 patent. At the time the applicant applied for the PTE, the PTO should have considered the date of expiration for the '565 patent as it would relate to the extended term of the '229 patent. Because the '565 patent is set to expire first, it is eligible to

[7] The Federal Circuit discussed the change in patent terms following the passage of the Uruguay Round, which changed the term from 17 years from issuance to 20 years from filing. The change in patent term calculation also necessitated a change in what references were eligible to serve as a double patent reference. The Federal Circuit recognizes in a footnote that, for pre-Uruguay Round patents, a patent issued later did not always expire later. For example, patents that qualified for a term extension may expire later although having issued first. Nevertheless, the Federal Circuit's mention of term extensions did not address the issues here.

serve as a double patenting reference for the ’229 patent. Thus, the ’229 patent extension is invalid under the doctrine of obviousness-type double patenting. 35 U.S.C. § 282(c).

V. CONCLUSION

For each of the reasons discussed above, Defendant Ezra Ventures LLC, respectfully requests that this Court enter an order invalidating the ’229 patent term extension in its entirety, or in the alternative, invalidate the extension for any time occurring after the expiration of the ’565 patent on September 23, 2017.

WHEREFORE, the Defendant Ezra Ventures LLC, respectfully requests that this Court enter an order invalidating the ’229 patent term extension in its entirety, or in the alternative, invalidate the ’229 patent term extension for any time occurring after the expiration of the ’565 patent on September 23, 2017, or for any other relief this Court deems just.

Dated: January 25, 2016

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CERTIFICATE OF SERVICE

I hereby certify that on January 25, 2016, I electronically filed the foregoing document with the Clerk of Court using the CM/ECF system, which shall send notification of such filing to all counsel of record.

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